Yale
NewHaven
Health
Bridgeport
Hospital

March 19, 2019

Heidi Caron, MSN, RN, BC, CLNC
Supervising Nurse Consultant
Department of Public Health
Facility Licensing & Investigation Section
410 Capitol Avenue, MS#12-FLIS
P.O. Box 340308
Hartford, CT 06134

Re: Complaint #24556, #24772

Dear Ms. Caron:

We have attached our response to your letter of March 15, 2019, listing the violations identified during the recent DPH/CMS visit. We believe we have addressed all of the deficiencies and have identified the measures that have been or will be taken, the dates those measures will be completed, and we have identified the responsible individuals.

Bridgeport Hospital appreciates that the Department of Public Health's efforts and insight have given us an opportunity to improve our systems of care and as a result the quality of the care we provide. We would like to thank you for your assistance in this regard.

Sincerely,

Ryan O'Connell, MD
Vice President, Performance/Risk Management
Interim CMO

ROC/dc

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THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following are violations of the Regulations of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

1. Based on medical record review, review of facility documentation, interviews, and policies, for three of ten patients who had histology testing performed, (Patient #1, Patient #2, and Patient #3), the facility failed to ensure that testing was performed properly to prevent cross contamination of specimens and/or failed to ensure polices/procedures were developed and/or implemented and/or that staff were trained and/or provided adequate supervision to ensure quality services in the subspecialty of histopathology. As a result of the system failure, Patient #1 received a hysterectomy on 12/28/18 based on a slide that was contaminated with pathological material from another patient (Patient #2).
   During the onsite visit on 2/11/19, it was verified that the hospital had not performed histopathology since 1/25/19 in accordance with thier allegation of compliance and as a result, immediate jeopardy was abated. The findings include:
   a. Patient #1 had a Hysteroscopy procedure on 12/3/18 with a biopsy obtained and was sent to pathology. Patient #1's pathology report dated 12/6/18 identified endocervical and endometrial curettings were positive for fragments of high grade serous carcinoma. On 12/28/18, Patient #1 had a robotic assisted total hysterectomy, bilateral salpingo-oophorectomy at Hospital #2. Review of the pathology report dated 12/28/18 of the gynecological tissue and lymph nodes removed during Patient #1's surgery identified no significant abnormality and/or benign lymph nodes. Further review identified that the error was discovered when Patient #1 had a hysterectomy on 12/28/18 at Hospital #2 when the tissue from the hysterectomy was examined and no tumor was identified. Hospital #2 re-examined Hospital #1's original histopathology slides and determined the tumor was present, therefore it was either entirely removed when the original specimens were collected or the specimens were mixed up or contaminated.
   Patient #2 had an Endometrial biopsy on 12/3/18. Review of the pathology report dated 12/7/18 identified serous carcinoma of the uterus and cervix. Review of the operative report dated 12/18/18 identified that the patient underwent a robotic-assisted total hysterectomy.
   Patient #3 had a blue light cystourethroscopy on 12/3/18. Review of the pathology report dated 12/7/18 identified that two floater cells of serous carcinoma gynecological tissue were noted and considered contaminated.
   Review of facility documentation dated 12/4/18 indicated that Patient #2's tissue sample was embedded (Embedding is the process in which the tissues or the specimens are enclosed in a mass of the embedding medium using a mold), Patient #3's tissue sample was embedded next and Patient #1's tissue sample was embedded lastly with the use of forceps and tampers (unique tools for flattening tissue sections in an embedding mold).
   Review of the Department Chair Meeting minutes dated 1/17/19, indicated that on 12/28/18, a patient (Patient #1) received a hysterectomy based on a slide contamination later determined to be pathologic material from another patient (Patient #2). Review of the office notes from Patient #1's gynecological physician dated 1/18/19 noted that Patient #1 and the patient's husband were informed of the pathology lab error.

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Review of the hospital proximity report from CoPath (laboratory information system) identified that on 12/4/18, the specimens that were embedded at the same time revealed that another case, Patient #2, was identified with serous carcinoma. Patient #2's case was embedded first and the middle case between Patient #1 and Patient #2 was a bladder biopsy (Patient #3). Patient #3's slide was re-examined and it was determined a small piece of serous cancer was present on the periphery of the slide and had no bearing on the final diagnosis for Patient #3.

Review of the genotyping done on Patient #1's original specimens determined the serous cancer was not that of Patient #1, but that of Patient #2. Patient #2's follow-up hysterectomy yielded a diagnosis of serous cancer. Further review identified that when it was determined specimens were contaminated, Hospital #1 ceased processing of surgical pathology specimens (exception of frozen sections) on 1/11/19.

Review of the Root Cause Analysis which began on 1/16/19 determined the tamper used at embedding was most likely the cause of the cross contamination.

Interview with Hystotechnologist #1 on 1/22/19 at 11:36 AM identified that s/he utilized forceps and tampers to imbed the tissues of Patient #1, Patient #2 and Patient #3 on 12/4/18. Hystotechnologist #1 indicated that although it was his/her practice to wipe off forceps and tampers prior to embedding the next patient's tissue, tissue could have been left on the tamper or the hot imbedding plate.

Additional interview with Histotechnologist #1 on 1/24/19 at 1:30 PM indicated that tampers are kept on the heating block/plate and if a tamper is used, it is placed on top of the specimen in the paraffin mold, then removed and placed back on the heating plate to melt the paraffin away and the bottom is wiped with a Kim-wipe between specimens. In addition, sometimes an embedder may need to press down to get the specimen on the same plate when using a tamper. Histotechnologist #1 further indicated that on 12/4/18 it was possible that some of the prior patient's specimen (Patient #2) went up the side of the tamper when she pressed the sample down onto the slide and only the specimen on the bottom came off when wiping resulting in the residual specimen carried over to the next two patients (Patient #1 and Patient #3).

Interview with the Laboratory Director on 1/22/19 at 9:56 AM identified that 2 of 3 patients had their tissue blocks cross contaminated during the tissue embedding process on 12/4/18 the Histotechnologist incorrectly utilized the tamper embedding tool which resulted in the cross contamination of paraffin embedded blocks. This resulted in an incorrect diagnosis of histopathology slides for Patient #1.

Interview with the Medical Director of the Laboratory on 1/22/19 at 10:50 AM noted that a "Kim-wipe is used to clean off each instrument in between patient use. Although the facility policy for routine embedding dated 7/2008 directed forceps are used and tissue tamps may be used to apply pressure and/or to exert an equal distribution force, the policy does not direct to wipe off after each patient use and directs to periodically wipe forceps and tampers during the embedding process to avoid carry-over from sample to sample 2.

b. Review of the hospital policy entitled "Embedding-Routine Embedding procedure" on 1/22/19 with the Histology Section Supervisor #1 identified that Procedure Step #8: "Using

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warmed forceps, apply gentle but equal pressure to the specimen so that it is flush against surface of mold, while moving the mold to a cooling area. There are tissue tamps that are available which have a larger surface area to exert an equal distribution of force ... Forceps and/or tampers should be wiped periodically during the embedding process to avoid carry-over from sample to sample." Further review failed to identify that a step by step procedure for proper use of 'tissue tamps' was not included and a step by step procedure for cleaning of forceps and/or tampers was not included.
Review of the Policy entitled, "Maintaining Specimen Identity" procedure on 1/28/19 with the Histology Section Supervisor #1 revealed the policy did not address the use of tissue tampers. Review of the "Routine Embedding Procedure" on 1/22/19 identified that the proper use and cleaning of tissue tampers between specimens was not addressed.

c. Review of the personnel file for Histotechnologist #1 identified that she has been employed since May 12, 2008 and currently performs embedding, sectioning and staining of tissue specimens. The facility was unable to provide documentation that Histotechnologist #1 had embedding process training.

d. Review of the laboratory's organizational chart "Department of Pathology & Laboratory Medicine Organizational Chart (CLIA)" revealed the hospital had two General Supervisors for histopathology. Review of the two histopathology General Supervisor's credentials revealed the following educational qualifications:
   i. Histopathology general supervisor #1 holds a Master of Science degree.
   ii. Histopathology general supervisor #2 holds a Bachelor of Science degree.
   Review of the CLIA regulation requirement directed that the General Supervisor should be a licensed physician certified in anatomic or clinical pathology.
   The hospital failed to ensure the General Supervisors met the educational qualifications as stipulated in the CLIA regulations.

e. Review of the training documentation on 1/24/19 for 2 of 2 new grossing testing personnel identified that the initial training form is a "competency assessment form" for the 6 required elements and was reviewed and signed by the laboratory director. Further review identified that training documentation of the development of the knowledge and skill to perform macroscopic gross examination of tissue specimens was not available.

f. Review of personnel files for histology staff for 2017 and 2018 competency records on 1/23/19 revealed competency documentation for 9 of 9 personnel for the use of tissue tampers was not available.

g. Interview and review of hospital documentation with the histology section supervisor #1 on 1/23/19 at 10:45 AM identified that the laboratory's signed CMS 209 form revealed 23 general supervisors listed with no specialties indicated. Further review identified that the laboratory's CMS 116 form signed 1/28/19 revealed the specialty/subspecialty of pathology and histopathology with an annual volume of 49,491 tests. The hospital failed to document the specialties of each General Supervisor.

h. Interview with the Laboratory Director on 1/29/19 at 4:10 PM identified that Histology Lab Aide #1's (HLA#1) employee records on 1/23/19 indicated that the initial documentation of histology job competency verification for tissue embedding was signed by histology section

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supervisor #2 on 2/24/17. Further review identified that the verification form for the tissue embedding task states, "Reduces cross contamination of tissue from block to block ("floaters") by using clean molds and keeping work surfaces free of debris and excess paraffin, "however, the tissue tamper training documentation was not available. Interview with HLA#1 on 1/23/19 at 1:05 PM identified that he/she was trained to embed tissue specimens in 2017 and was embedding in 2017 and throughout 2018.

i. Interview with the Histopathology Technical Supervisor on 1/24/19 at 11:35 AM identified that a Pathologist Assistant (PA#1) performed the training of the 2 of 2 new grossing testing personnel. Further review identified that PA #1's training documentation was not available. Interview with the Grossing Testing Personnel #1 (GTP#1) on 1/28/19 at 3:40 PM identified that GTP#1 started grossing small biopsy specimens May 2017 and was trained by PA#1. Further review identified that training documentation was not available.

dc
3/19/19
4AE1

POC Acceptable
E. Kronenberger
3/24/19

Bridgeport Hospital – 070010
DPH Violation Letter 3-15-19 / Date of Visit 2-11-19

3/19/19

DPH Violation #	Provider Plan of Correction	Completion Date
1	Bridgeport Hospital has not performed histopathology since 1/25/19.	1/25/19
	• As of 5 pm on 1/11/2019, all histopathology processing, with the exception of Frozen Sections, was suspended at Bridgeport Hospital.	1/11/19
	• A Root Cause Analysis (RCA) was performed.	1/23/19
	• As of 2:00 PM on 1/24/2019, frozen section processing was additionally suspended.	1/24/19
	• During this period of suspension for the processing of frozen and non-frozen histopathology, policies and procedures have been reviewed and revised as appropriate for all steps of the preparation process. Education and competencies for all staff who would perform this process have been completed and documented. A validation study using parallel processing was completed for frozen and non-frozen histopathology.	2/27/19
	In order to maintain adequate laboratory services to meet the needs of its patients the following was put into place and will be ongoing until processing at Bridgeport Hospital resumes.	
	• As of 1/15/2019 at 1:00 PM, all non-frozen tissue samples are being sent to Yale New Haven Hospital for processing.	1/15/19
	• A policy entitled "Procedure for Sending Tissue for Processing at Other System Hospital" was created and training was provided to all appropriate laboratory staff.	2/8/19
	Monitoring Plan: In order to proactively identify any potential delays, a concurrent patient impact study for delay of diagnosis is being performed. Elements include: • A log of calls from clinicians regarding delayed results and potential impact is being kept. • Cases that are signed out greater than 10 days after being processed elsewhere are reviewed for significant or unexpected diagnoses that might have potential to affect patient care. Chart review in Epic is completed to assess real impact. Clinicians are called for follow-up as needed. • Delays resulting in patient impact will be discussed at the Anatomic Pathology Quality Assurance meeting and reported to Quality Council and the Professional and Quality Committee of the Board of Directors.	

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	In addition: • Bridgeport Hospital cases sent to other System Hospitals are reviewed by Yale Medicine Pathologists. Those Yale Medicine Pathologists conduct quality assessment of slides daily according to the policies and procedures of the respective Hospital laboratories. • Quality Assurance assessments are forwarded back to Bridgeport Hospital for review at the Bridgeport Hospital Anatomic Pathology Quality Assurance meeting. Responsible: Histopathology Technical Supervisor Patient impact: Current policy is that all cases in which there is a discrepancy between current and prior pathologic material triggers a review of the prior material to resolve or explain the discrepancy. Therefore, all instances wherein a cancer operation fails to reveal a previously diagnosed cancer would trigger an extremely high degree of concern and would be investigated, as was true for the Index Case. All reports from 1/1/18 – 1/14/19 were reviewed for diagnoses of malignancies. No erroneous results other than the index case were identified. Responsible: Histopathology Technical Supervisor	2/10/19
1a,b,c	Bridgeport Hospital has not performed histopathology since 1/25/19. • A Root Cause Analysis (RCA) was performed. **For non-Frozen Sections:** The following steps have been put in place to prevent recurrence: • Tampers are no longer being used in the histology embedding process. • Policy for Routine Embedding has been revised to minimize risk of "floaters". Included is removal of the use of tampers and proper cleaning of forceps and embedding surface between blocks. • Histotechnology staff have been educated on the policy and procedure and this education was documented. • Histotechnology staff competency for embedding has been completed, assessed via simulation using non-diagnostic practice blocks. Histopathology policies and procedures pertaining to the other steps in the process including grossing, microtomy and routine staining have also been reviewed and revised as appropriate to minimize risk of cross contamination. For each step of the process, education of all	1/25/19 1/23/19 2/10/19

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	staff and competency assessments have been completed and documented.	2/10/19
	• A Validation study was performed using parallel processing for 100 preserved specimens for all steps in specimen processing.	2/26/19
	Monitoring Plan: Upon resumption, a checklist will be completed for 50 specimens per week for six months to include the following elements: • The integrity and identity of the tissues in the submitted blocks will be verified for these cases for grossing, embedding and microtomy • Use of barcodes • Use of clean forceps each case • Wiping forceps between blocks of the same patient • Cleaning of embedding surface • Wiping of water bath between blocks • Forceps and molds put through cleaning cycle at the end of each day After the initial six months, five randomly selected specimens will be audited per month for compliance. Results of the initial and ongoing monitoring will be reported to the Anatomic Quality Assurance Committee. Responsible: Histopathology Technical Supervisor	
	For Frozen Sections:	
	• Histotechnologists and Pathologists who are performing frozen sections have been educated on the frozen section policy and procedure and competency has been completed. No personnel will independently perform frozen sections until they have passed competency assessment.	2/10/19
	• An external Board Certified pathologist and an American Society of Clinical Pathology-Certified Histotechnologist were engaged to proctor the pre-analytical processing and handling of Frozen Sections.	1/25/19
	• The engaged proctoring pathologist and histotechnologist performed a competency assessment of all Bridgeport Hospital pathologists performing the procedure.	1/25/19
	• Upon resumption of histopathology, all pathology interpretations will be validated and verified (formal 'time out') by a second pathologist for all frozen section specimens for a 3 month period.	

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	1. If there is a discrepancy between the assessments of the frozen sections by the two pathologists, a third pathologist will be consulted. 2. Off hours, the case will be photographed and an email with the case photos will be sent to another consulting pathologist for confirmation of the diagnosis and slide quality. • The histopathology department maintains two cryostats for performing frozen sections. If two frozen sections are being performed at the same time, separate cryostats will be used for the two patients. • The procedure for performing frozen sections has been revised in order to emphasize the importance of cleaning the working areas of the cryostat during and after each frozen section to avoid cross-contamination. • A validation study utilizing 10 non-diagnostic tissue will be conducted in parallel with Yale New Haven Hospital. The results will be documented on the frozen section log. **Monitoring Plan:** Upon resumption, the process for all frozen sections will be audited for compliance. Once per week for six months, a direct observation will be performed of a selected frozen section case. The auditing results will be reported out at the Anatomic Pathology Quality Assurance Committee. Responsible: Histopathology Technical Supervisor	1/25/19 1/25/19 2/26/19
	Monitoring for Floaters upon resumption: 1. The existing Yale Medicine 'Handling of Floaters' policy has been revised as a Bridgeport Hospital laboratory policy to reflect the items below with education provided to the Pathologists. • Each pathologist will review slides with attention to identifying floaters. • A Monthly Floater Log sheet was created and each pathologist will maintain a monthly paper log of all floaters identified, regardless of potential impact. • The logs will be collected at the end of each month and will be reviewed for patterns of occurrence, such as where the floaters likely occurred in the process of tissue handling. • The results will be discussed as a routine agenda item at the Anatomic Pathology Quality Assurance meetings beginning upon resumption of histopathology.	2/6/19

DPH Violation #	Provider Plan of Correction	Completion Date
	2. A policy titled "Addendum to Handling Floaters-Neoplastic Tissue" has been developed and pathologists have been educated on the new policy. The policy includes: • Upon resumption of embedding, any potential clinically significant floater will be photographed by the pathologist who identifies it, who will then email the photograph to other Pathologists in the department, both at Bridgeport and at Yale New Haven Hospital, and will be recorded on the monthly Floater Log sheet.	2/6/19
	3. A policy for a daily Consensus Conference for the pathologists on-site at Bridgeport Hospital has been developed and Pathologists have been educated. The policy includes: • Upon resumption of histopathology, all newly diagnosed cancer cases will be presented to the pathologists prior to sign-out, allowing identical tumors to be noticed and contaminants identified prior to sign-out. A logbook will be kept for recording of all consensus cases and any issues that arise will be reported to the Anatomic Pathology Quality Assurance Committee. Responsible: Histopathology Technical Supervisor	2/6/19
	• A summary of the monthly Anatomic Pathology Quality Assurance meeting will be presented monthly at Quality Council and Professional and Quality Committee of the Board, and at every full Board meeting, with a more in depth discussion of any significant issues, for at least one year. • The Professional & Quality Committee of the Board and the hospital Quality Council have received a memo describing the initial patient impact study and minutes from the January ad hoc meeting of the Anatomic Pathology Quality Assurance Committee. Responsible: Interim Chief Medical Officer	2/10/19 2/10/19
1d	• An experienced, board-certified anatomic and clinical pathologist (MD) based at Bridgeport Hospital has assumed the overall management and direction for laboratory services at Bridgeport Hospital. • A new laboratory director has been identified and will serve as the general supervisor for histopathology who meets all qualifications for this role. • The new general supervisor is qualified to serve as such based on cfr.493-1461. The new General supervisor is a doctor of medicine, licensed to practice in the state of Connecticut,	2/11/19

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	Board certified in Anatomic and Clinical Pathology and is qualified to be laboratory director and technical supervisor in the subspecialty of histopathology. The new Laboratory Director's responsibilities will include: • Ensuring quality laboratory services for all aspects of performance including pre-analytic, analytic and post analytic phases of testing. • Ensuring that the laboratory personnel are performing the test methods as required for accurate and reliable results. • Ensuring that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. • Ensuring that prior to testing patient specimens all personnel will have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, have demonstrated that they can perform all test and operations reliably to provide and report accurate results. • Ensuring that policies and procedures are established to monitor individuals who conduct pre analytical, analytical, and post analytical phases of testing to ensure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. • Serving as the technical supervisor for histopathology and will be responsible for establishing and maintaining a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen through sample analysis and reporting of test results. • Serving as the technical supervisor for histopathology and will identify training needs to assure each individual performing tests receive regular in-service training and education appropriate for the type and complexity. **Monitoring Plan:** The new laboratory director/technical supervisor/general supervisor has completed an annual competency assessment by another pathologist qualified to be a laboratory director. Responsible: Laboratory Director	2/10/19

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1e	• Histopathology policies and procedures pertaining to grossing, microtomy and routine staining were reviewed and revised to minimize risk of cross contamination and the Histotechnology staff have been educated on the revised and approved policies and procedures. • Histotechnology staff competencies have been assessed via simulation using non-diagnostic practice blocks and documented. • A new laboratory director has been identified and will serve as the general supervisor for histopathology. The new laboratory director will ensure that prior to testing patient specimens all personnel will have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, have demonstrated that they can perform all test and operations reliably to provide and report accurate results. Responsible: Laboratory Director	2/10/19 2/11/19
1g	• The "Directors Designee Form" for each general supervisor does include their specialty. • The Competency Check List form for each of the general supervisors has been revised to also include their specialty. • Instructions for form CMS 209 only indicates technical consultant/technical supervisors (TC/TS) need to have the individual's specialty/subspecialty recorded. In the future we can also record the specialties for each General Supervisor (GS). Responsible: Laboratory Director	2/19/19
1h,f	• Policy for Routine Embedding has been revised to minimize risk of "floaters". Included is removal of the use of tampers and proper cleaning of forceps and embedding surface between blocks. • Histotechnology staff have been educated on the policy and procedure and this education was documented. • Histotechnology staff competency for embedding has been completed, assessed via simulation using non-diagnostic practice blocks. • A new laboratory director has been identified and will serve as the general supervisor for histopathology who meets all qualifications for this role. • The new general supervisor is qualified to serve as such based on cfr.493-1461. The new General supervisor is a doctor of	2/10/19 2/11/19

DPH Violation #	Provider Plan of Correction	Completion Date
	medicine, licensed to practice in the state of Connecticut, Board certified in Clinical and Anatomic Pathology and is qualified to be laboratory director and technical supervisor in the subspecialty of histopathology. The new laboratory director ensures that prior to testing patient specimens all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, have demonstrated that they can perform all test and operations reliably to provide and report accurate results. Responsible: Laboratory Director	
1i	• Pathology Assistant has been educated on the revised and approved grossing policy and procedure and competency has been assessed. No other pathology assistants will be allowed to perform grossing until they have been educated and competency assessed. The new Laboratory Director's responsibilities will include: • Ensuring that prior to testing patient specimens all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, have demonstrated that they can perform all test and operations reliably to provide and report accurate results • Serving as the technical supervisor for histopathology and will identify training needs to assure each individual performing tests receive regular in-service training and education appropriate for the type and complexity and training will be documented. Responsible: Laboratory Director	2/10/19 2/11/19

3/19/19

Ryan O'Connell, MD
V.P. Performance Management / Interim CMO
Bridgeport Hospital

3/19/19

Harold Sanchez, MD
Laboratory Director
Bridgeport Hospital